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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,864	CASTELLI ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2-8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/12/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The election with traverse filed September 10, 2007, is acknowledged and has been entered.

Applicant has elected the invention of Group I, claims 1 and 9-14, drawn to an immunogenic peptide of SEQ ID NO:1 and compositions comprising said peptide.

2. Claims 1-14 are pending in the application.

3. Claims 2-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 10, 2007.

4. Claims 1 and 9-14 are under examination.

Election/Restrictions

5. Applicant's traversal of the restriction and election requirement set forth in the Office action mailed July 10, 2007 is acknowledged.

Applicant's arguments have been carefully considered but have not been found persuasive for the following reasons:

The traversal is on the grounds that the Novellino et al reference is not available as prior art according to PCT Rule 13.2 and Rule 64.1 as Novellino et al was published after the international application, Italy MI2002A002412.

In response, the international application, Italy MI2002A002412 upon which Applicant relies is not written in English and Applicant has not supplied a verified or certified translation of the priority document in English. Thus priority[1] has only been

[1] See below discussion pertaining to the priority date granted the instant claims

established to the filing date of PCT/EP03/12638, i.e., November 12, 2003, and as Novellino et al was published on June 15, 2003, it is available as prior art.

Notably, PCT Rule 51bis.1, sections D and E state the following:

> (d) The national law applicable by the designated Office may, in accordance with Article 27(2)(ii), require that the translation of the international application furnished by the applicant under Article 22 be:
> (i) verified by the applicant or the person having translated the international application in a statement to the effect that, to the best of his knowledge, the translation is complete and faithful;
> (ii) certified by a public authority or sworn translator, but only where the designated Office may reasonably doubt the accuracy of the translation.
> (e) The national law applicable by the designated Office may, in accordance with Article 27, require the applicant to furnish a translation of the priority document, provided that such a translation may only be required where the validity of the priority claim is relevant to the determination of whether the invention concerned is patentable.

Furthermore, with respect to the definition of "prior art", PCT Rule 27(5) states the following:

> In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.

Accordingly, Novellino et al is available as prior art.

Therefore, for these reasons and the reasons set forth in the Office action mailed July 10, 2007, these inventions do not share unity of invention as required under PCT Rule 13 and the restriction/election requirement is deemed proper and therefore made FINAL.

Information Disclosure Statement

6. The references cited in the information disclosure statement filed on May 12, 2005, have been considered.

Priority

7. Applicant's claim under 35 USC §§ 119 and/or 120 for benefit of the earlier filing date of the foreign application Italy MI2002A002412 filed November 14, 2002, is acknowledged.

In this case, while a certified copy of foreign application Italy MI2002A002412 has been placed of record in the file, Applicants have not provided a verified or certified translation of document Italy MI2002A002412. Therefore, the effective filing date of the instant claims is the filing date of PCT/EP03/12638, i.e., November 12, 2003. See 37 CFR 1.55. See MPEP § 201.15.

Notably, when Applicant relies upon a document in a language other than English 37 CFR § 41.154 states:

> When a party relies on a document or is required to produce a document in a language other than English, a translation of the document into English and an affidavit attesting to the accuracy of the translation must be filed with the document.

Additionally, the claims do not properly benefit under 35 U.S.C. §§ 119 and/or 120 by the earlier filing dates of the priority documents claimed, since those claims are rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate written description and a sufficiently enabling disclosure.

Accordingly, the effective filing date of the claims is deemed the filing date of PCT/EP03/12638, i.e., November 12, 2003.

Specification

8. The disclosure is objected to because of the following informalities:

a. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be

respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

An example of such an improperly demarcated trademark appearing in the specification is GenBank® (see numerous instances, e.g., page 8, line 6). Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

b. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

9. Claims 9-14 are objected to as being drawn to the subject matter of a non-elected invention; i.e., claims 9-14 are directed in the alternative to the subject matter of the non-elected invention of Group III.

Claim Rejections - 35 USC § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is drawn to "the $PTPRK_{Gly677 \rightarrow Arg682}$ immunogenic peptide of SEQ ID NO: NO: 1", which is not necessarily isolated. Therefore, absent a showing of any

difference, the claims are broadly interpreted to encompass polypeptides comprising or consisting of the amino acid sequence of SEG ID NO:1, which are naturally occurring and comprised within an organism, including a human.

Support for this interpretation is found in the specification that teaches isolating an antigenic epitope from a human melanoma patient and that the amino acid sequence of this peptide consists of SEQ ID NO:1 (see entire document, e.g., page 3, lines 2-20). As such, absent a showing of any difference, the claims encompass naturally occurring polypeptides.

In the absence of the hand of man, the naturally occurring polypeptides are considered non-statutory subject matter. See *Diamond v. Chakrabadv*, 206 U.S.P.Q. 193 (1980)).

Moreover, given the fact that the peptide is naturally comprised within a human, the claims might broadly but reasonably be interpreted to encompass a human being (or at the very least, a part thereof that has not been isolated). Accordingly, Applicant is reminded that MPEP § 2105 [R-1] states:

> If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter.

This issue may be remedied by amending the claims to recite a limitation requiring the "immunogenic peptide" to be "isolated".

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 1 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 9-14 are indefinite for the following reasons:

(a) Claim 1 recites: "The $PTPRK_{Gly677 \rightarrow Arg682}$ immunogenic peptide of SEQ ID NO: 1". However, since SEQ ID NO: 1 is an amino acid sequence, it does not comprise a peptide, per se. A protein or polypeptide might comprise a peptide, or more particularly an "immunogenic peptide". Additionally, SEQ ID NO: 1 consists of only 16 amino acids and therefore does not have an amino acid at position 677 or 682. So it is unclear how claim 1 should be read. Moreover, it is unclear if claim 1 is to be construed to encompass some peptide fragment having an amino acid sequence that is a mere portion of SEQ ID NO: 1 (or a peptide comprising, or consisting of that sequence) having the designation "$PTPRK_{Gly677 \rightarrow Arg682}$", or perhaps a peptide consisting of the amino acid sequence of SEQ ID NO: 1.

(b) Claim 9-14 are indefinite for reciting "peptide SEQ ID NO:1" in claims 9, 11 and 13. A peptide is a polymer of amino acids arrayed in a linear sequence; as such, a peptide may be described as comprising or consisting of the amino acid sequence of SEQ ID NO:1, but it is not SEQ ID NO:1, *per se*. Thus, without delineating whether the peptide comprises or consists of the recited amino acid sequence, the metes and bounds of the subject matter that is regarded as the invention cannot be determined. Does the peptide comprise the amino acid sequence of SEQ ID NO:1, consist of the amino acid of SEQ ID NO:1 or is some other peptide contemplated? Accordingly, claims 9-14 fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite clarity and particularity to permit the skilled artisan to know or determine infringing subject matter.

Amending claims 9, 11, and 13 to recite, for example, that the peptide comprises, or consists of the amino acid sequence of SEQ ID NO:1 would obviate this ground of rejection.

(c) Claims 12 and 14 are indefinite for reciting "$PTPRK_{Gly677 \rightarrow Arg682}$". This recitation renders the claims indefinite as it cannot be ascertained what this designation

is referring to. For example, does this designation refer to a polypeptide with Gly677 somehow replaced with Arg682, a peptide comprising amino acids 677-682 of a PTPRK polypeptide with Gly at position 677 and Arg at position 682, or some other polypeptide and/or peptide? Again, SEQ ID NO:1 consists of only 16 amino acids and therefore does not have an amino acid at position 677 or 682, and therefore one of skill in the art would not be reasonably apprised of the metes and bounds of the claims to know or determine infringing subject matter.

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 1 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the

applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

Claims 1 and 9-14 are drawn to a structurally and functionally diverse genus of "$PTPRK_{Gly677 \rightarrow Arg682}$ immunogenic peptides of SEQ ID NO:1" and compositions comprising "the peptide SEQ ID NO:1".

However, as explained in the above rejection of claim 1 under 35 U.S.C. § 112, second paragraph, since SEQ ID NO: 1 is an amino acid sequence, it does not comprise a peptide, per se. A protein or polypeptide might comprise a peptide, or more

particularly an "immunogenic peptide". Additionally, SEQ ID NO: 1 consists of only 16 amino acids and therefore does not have an amino acid at position 677 or 682. So it is unclear how claim 1 should be read. Moreover, it is unclear if claim 1 is to be construed to encompass some peptide fragment having an amino acid sequence that is a mere portion of SEQ ID NO: 1 (or a peptide comprising, or consisting of that sequence) having the designation "$PTPRK_{Gly677\rightarrow Arg682}$", or perhaps a peptide consisting of the amino acid sequence of SEQ ID NO: 1.

Therefore, the structure of the claimed immunogenic peptide cannot be known with certainty.

Then, as further explained in the above rejection of claims 9-14 under 35 U.S.C. § 112, second paragraph, it cannot be determined if the peptide comprises, or consists of the amino acid sequence of SEQ ID NO: 1.

Nonetheless, in the interest of advancing prosecution, it is presumed that claims 9-14 are directed to a peptide comprising the amino acid sequence of SEQ ID NO: 1.

As such the claims are directed to a genus of structurally disparate peptides that are merely described as having an amino acid sequence that comprises the amino acid sequence of SEQ ID NO: 1, which again is only 16 amino acids in length. The claims do not require that the peptide possess any particular biological activity, nor any particular conserved structure, or other disclosed distinguishing feature and therefore there is no correlation of any particular identifying structural feature with any function shared by members of there genera.

In this instant case the specification only provides evidence that a 16 amino acid peptide consisting of the amino acids sequence of SEQ ID NO:1 was isolated as an antigenic epitope from a human melanoma patient (see entire document, e.g., page 3, lines 2-20).

Therefore, as further explained in the above rejections of the claims under 35 U.S.C. §§ 101 and 112, second paragraph, it cannot be ascertained whether the "$PTPRK_{Gly677\rightarrow Arg682}$ immunogenic peptide of SEQ ID NO:1" is necessarily *removed or isolated from* a human or still comprised in a human nor can the amino acid sequence of such peptides be determined. Applicant is reminded that although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If the peptides are not necessarily isolated and do not consist of the amino acid sequence of SEQ ID NO:1, it cannot be ascertained what structural and/or functional features distinguish members of the "$PTPRK_{Gly677 \rightarrow Arg682}$ immunogenic peptides of SEQ ID NO:1" genus or "the peptide SEQ ID NO:1" genus from any others. Thus, unless the peptides are necessarily isolated and consist of the amino acid sequence of SEQ ID NO:1, it is submitted that the disclosure would not permit the artisan to immediately envision, recognize or distinguish the claimed invention; and as such, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

16. Claims 1 and 9-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, **while being enabling for making and using** an isolated immunogenic peptide consisting of the amino acid sequence of SEQ ID NO:1, **does not reasonably provide enablement for making and using** the claimed invention, such as, for example, immunogenic peptides comprising or consisting of the amino acid sequence of SEQ ID NO:1 that are not isolated, **and does not reasonably provide enablement for making and using** pharmaceutical compositions, medicaments or diagnostic compositions comprising a peptide consisting of the amino acid sequence of SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

MPEP § 2164.01 states:

> The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled

> so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors, which have been outlined in the Federal Circuit decision of *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), include, but are not limited to, the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed. See also *Ex parte Forman*, 230 USPQ 546 (BPAI 1986).

The amount of guidance, direction, and exemplification disclosed in the specification, as filed, would not be sufficient to enable the skilled artisan to make and/or use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claims 1 and 9-14 are drawn to a structurally and functionally diverse genus of "$PTPRK_{Gly677\rightarrow Arg682}$ immunogenic peptides of SEQ ID NO:1" and compositions comprising "the peptide SEQ ID NO:1".

However, as explained in the above rejection of claim 1 under 35 U.S.C. § 112, second paragraph, since SEQ ID NO: 1 is an amino acid sequence, it does not comprise a peptide, per se. A protein or polypeptide might comprise a peptide, or more particularly an "immunogenic peptide". Additionally, SEQ ID NO: 1 consists of only 16 amino acids and therefore does not have an amino acid at position 677 or 682. So it is unclear how claim 1 should be read. Moreover, it is unclear if claim 1 is to be construed to encompass some peptide fragment having an amino acid sequence that is a mere portion of SEQ ID NO: 1 (or a peptide comprising, or consisting of that sequence) having the designation "$PTPRK_{Gly677\rightarrow Arg682}$", or perhaps a peptide consisting of the amino acid sequence of SEQ ID NO: 1.

Therefore, the structure of the claimed immunogenic peptide cannot be known with certainty.

Then, as further explained in the above rejection of claims 9-14 under 35 U.S.C. § 112, second paragraph, it cannot be determined if the peptide comprises, or consists of the amino acid sequence of SEQ ID NO: 1.

Nonetheless, in the interest of advancing prosecution, it is presumed that claims 9-14 are directed to a peptide comprising the amino acid sequence of SEQ ID NO: 1.

Then, as explained in the above rejection of the claims, as failing to comply with the written description requirement, the claims are drawn "$PTPRK_{Gly677 \rightarrow Arg682}$ immunogenic peptides of SEQ ID NO:1" that are not necessarily isolated and to compositions comprising the "peptide SEQ ID NO:1", which is inclusive of a structurally and functionally genus of peptides.

However, the specification only discloses that a 16 amino acid peptide consisting of the amino acids sequence of SEQ ID NO:1 was isolated as an antigenic epitope from a human melanoma patient (see entire document, e.g., page 3, lines 2-20).

Therefore, the specification does not reasonably enable the skilled artisan to make any member of the genus of peptides comprising the amino acid sequence of SEQ ID NO: 1, which otherwise need not have any particular structure or function.

Moreover, the specification does not enable the use of a peptide consisting of the amino acid sequence of SEQ ID NO:1, *unless it is isolated*, as one of skill in the art would be subject to undue experimentation to use such a peptide comprised in a human.

Furthermore, while the specification teaches one of skill in the art how to use an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 to make isolated antibodies that can recognize the peptide consisting of the amino acid sequence of SEQ ID NO:1 and that such antibodies can then diagnose melanoma patients (see specification at pages 4-5, bridging paragraph), the specification does not enable the use of an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 in a pharmaceutical composition, a pharmaceutical vaccine, a medicament for the

preventative or therapeutic treatment of melanoma or in a diagnostic composition to characterize melanoma.

In this case, the specification lacks any specific, non-general guidance on how to use an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 as a vaccine or a medicament to prevent or treat melanoma or how to use an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 to characterize melanoma. For example, the specification presents merely prophetic examples that peptides of the invention may be administered to patients orally, parenterally, subcutaneously or intramuscularly and that such treatments should be able to elicit a humoral or cell-mediated immune response directed against the tumor (see e.g., page 4, lines 7-14). Therefore, the specification in not enabling for pharmaceutical compositions, vaccines and medicaments for the preventive or therapeutic treatment of melanoma using the claimed peptides, or more particularly, an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 because it is highly unpredictable whether such a peptide can be used in a pharmaceutical composition, vaccine or medicament to prevent or treat melanoma and there are no working examples present in the specification that reasonably enable the use of such a peptide to prevent or treat melanoma.

For example, there is no teaching in the prior art or post-filing art indicating that any cancer can be prevented with a peptide vaccine. DeGruijl et al. (Nature Medicine, 5(10): 1124-1125, October 1999) state that a variety of anti-tumor vaccine trials have been undertaken and in spite of the large number of these trials, and the plethora of distinct approaches investigated, there has been little evidence of clinical efficacy. Bodey et al. (Anticancer Research 20: 2665-2676, 2000) teach that peptide vaccination against tumor antigens can induce a powerful systemic CTL response but no tumor regression was observed in a majority of the patients, see page 2673, left column, third complete paragraph. Mellman (The Scientist 20(1): 47, 2006) teaches that therapeutic vaccines for cancer have been disappointing with the response rate of roughly 1,000 patients is below 4%, see page 47, second paragraph. Therefore it is highly unpredictable whether any peptide could be used to prevent or treat melanoma and as

the specification lacks any working example showing that an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 prevents or treats melanoma in any model system, one of skill in the art would be subject to undue experimentation to practice the invention.

Furthermore, with respect to using the claimed peptides in a diagnostic composition to characterize melanoma, it is also submitted that the specification lacks any specific, non-general guidance on how to use an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 in a diagnostic composition to characterize melanoma. For example, at page 6, lines 5-9, the specification teaches that peptides of the invention can be used in the diagnosis of melanoma, for instance by PCR analysis or immunoassays using epitope-specific antibodies, yet the specification lacks any specific, non general guidance on how to use such peptides in these diagnostic methods. For example, as PCR analysis comprises amplifying polynucleotides, one of skill in the art would be subject to undue experimentation to use the claimed peptides in PCR analysis, as the specification provides no evidence that an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 is required for PCR analysis to diagnose melanoma. Furthermore, while the isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 can be used to make epitope-specific antibodies to diagnose melanoma, such a peptide is not used in the immunoassay *per se.* Therefore, one of skill in the art would be subject to undue experimentation to use the claimed peptides, or more particularly, an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 comprised in a diagnostic composition for characterizing melanoma.

In conclusion, upon careful consideration of the factors used to determine whether undue experimentation is required, in accordance with the Federal Circuit decision of *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988), the amount of guidance, direction, and exemplification disclosed in the specification, as filed, is not deemed sufficient to have enable the skilled artisan to make and/or use the claimed invention at the time the application was filed without undue and/or unreasonable experimentation.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

18. Claims 1 and 9-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Novellino et al (J. Imm., 170:6363-6370, June 15, 2003, IDS filed 5/12/2005).

The claims are herein drawn to an isolated immunogenic peptide consisting of the amino acid sequence of SEQ ID NO:1 and compositions comprising said isolated immunogenic peptide in an admixture with pharmaceutically acceptable excipients.

Novellino et al teach an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 (see entire document, e.g., Figure 7, second peptide from the top). Novellino et al further teach said peptide in aqueous compositions administered to cells that inherently comprise pharmaceutically acceptable excipients, such as water (see e.g., page 6345, right column, Figure 7 and Figure 9).

In summary, Novellino et al teach compositions comprising an isolated peptide consisting of the amino acid sequence of SEQ ID NO:1 that are structurally and functionally indistinguishable from the instantly claimed peptides and compositions comprising said peptide in an admixture with pharmaceutically acceptable excipients. Therefore, absent a showing of any difference Novellino et al anticipate these claims.

Applicant is reminded that because a translation of the foreign priority document has not been made of record in accordance with 37 CFR 1.55, Applicant cannot rely upon said document to overcome this rejection. See MPEP § 201.15.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

bd
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